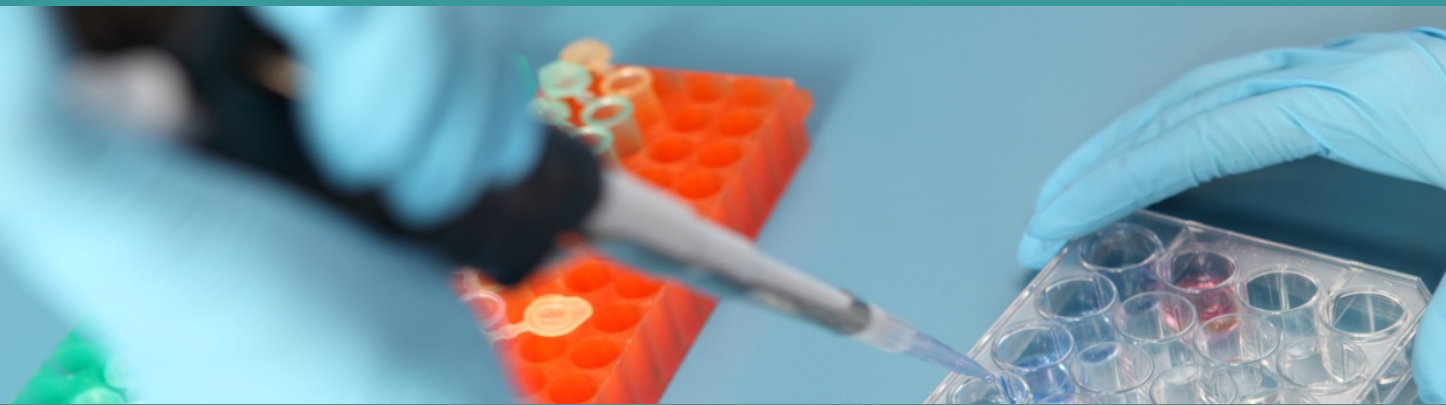




A NEW FRONTIER IN IMMUNO-ONCOLOGY

Proactive One2One Biotechnology Forum
LSE: SCLP.L

November 2018





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DIFFERENTIATED IMMUNO-ONCOLOGY CLINICAL STAGE OPPORTUNITY

COMPANY FOCUS

- Scancell is developing innovative immunotherapies for the treatment of cancer

MARKET OPPORTUNITY

- Immuno-oncology is one of the fastest growing sectors in the biopharmaceutical industry (est. CAGR ~20% over next 5 years)

PROPRIETARY TECHNOLOGY PLATFORMS

- Novel immunogenic antigens and modulation mechanisms that stimulate potent T-cell responses for the treatment or prevention of cancer
- Unique mode of action of **IMMUNOBODY**[®] and **MODITOPE**[®] immunotherapies stimulate immune responses by presenting cancer antigens to trigger potent killer T-cell activation

CLINICAL STAGE ASSETS

- Four lead products in development
- Phase II and Phase I/II studies in preparation targeting multiple cancer indications

COMPANY FACTS & FINANCIALS

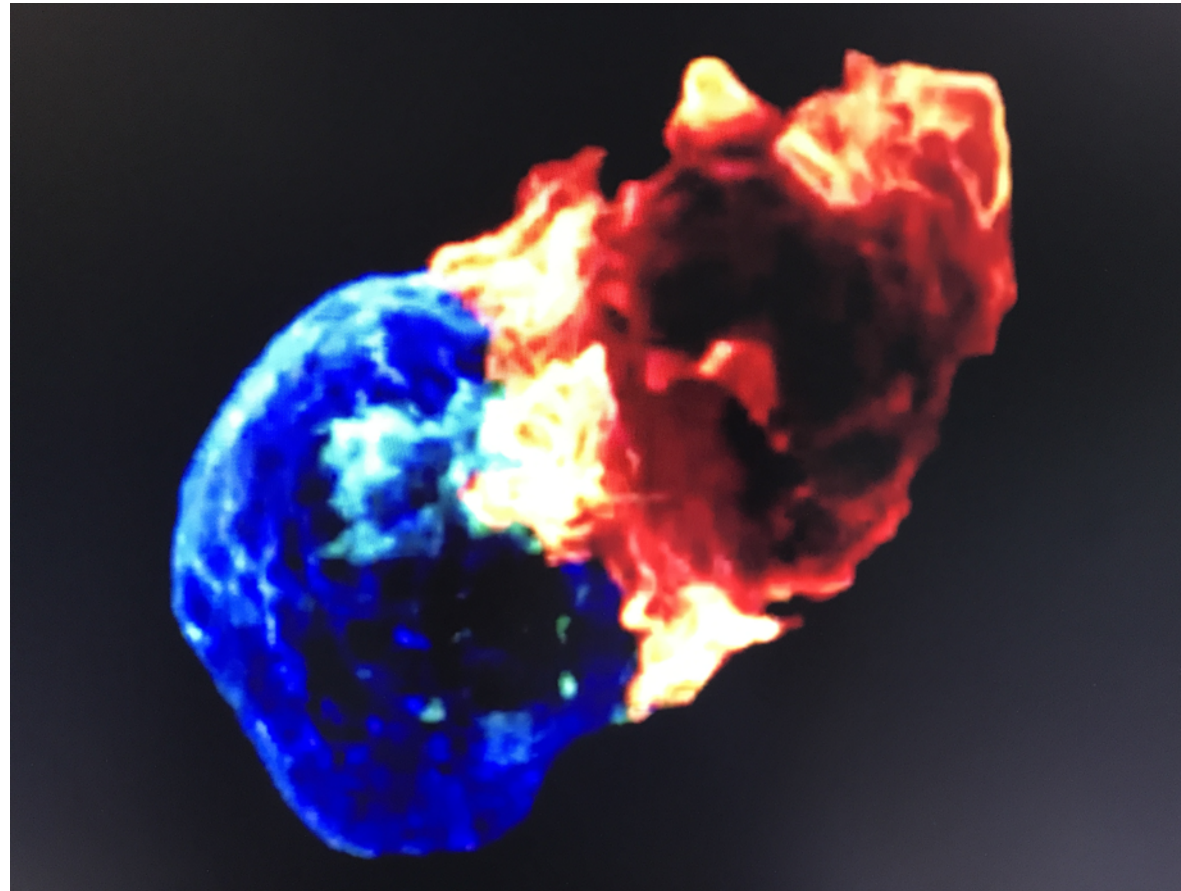
- Scientific founder Professor Lindy Durrant
- Corporate offices based in Oxford, UK
- 23 employees (10 PhD's)
- AIM listed (SCLP)

2 PLATFORMS, 4 LEAD PRODUCTS + MULTIPLE CANCER INDICATIONS



P/RMA
RESEARCH • PROGRESS • HOPE

Cells #GOBOLDLY



“This is not a video game” - US TV ad showcases the destruction of a cancer cell by immune system



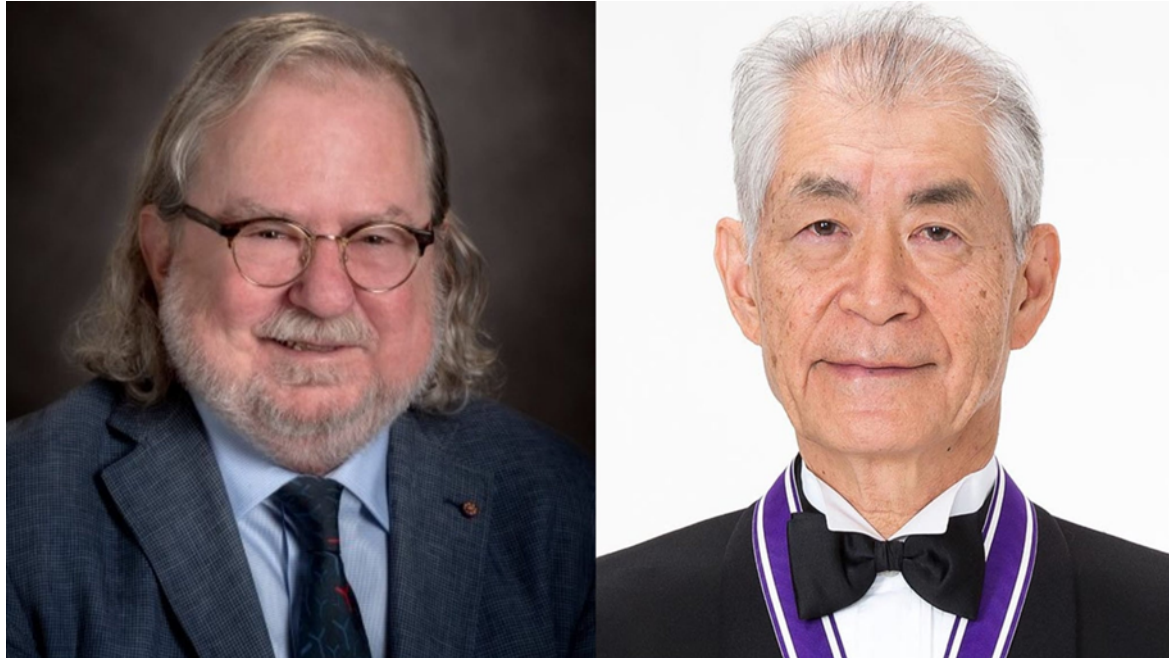
IMMUNOTHERAPEUTIC APPROACHES TO CANCER

Harnessing the immune system to address the unmet need in improved cancer survival

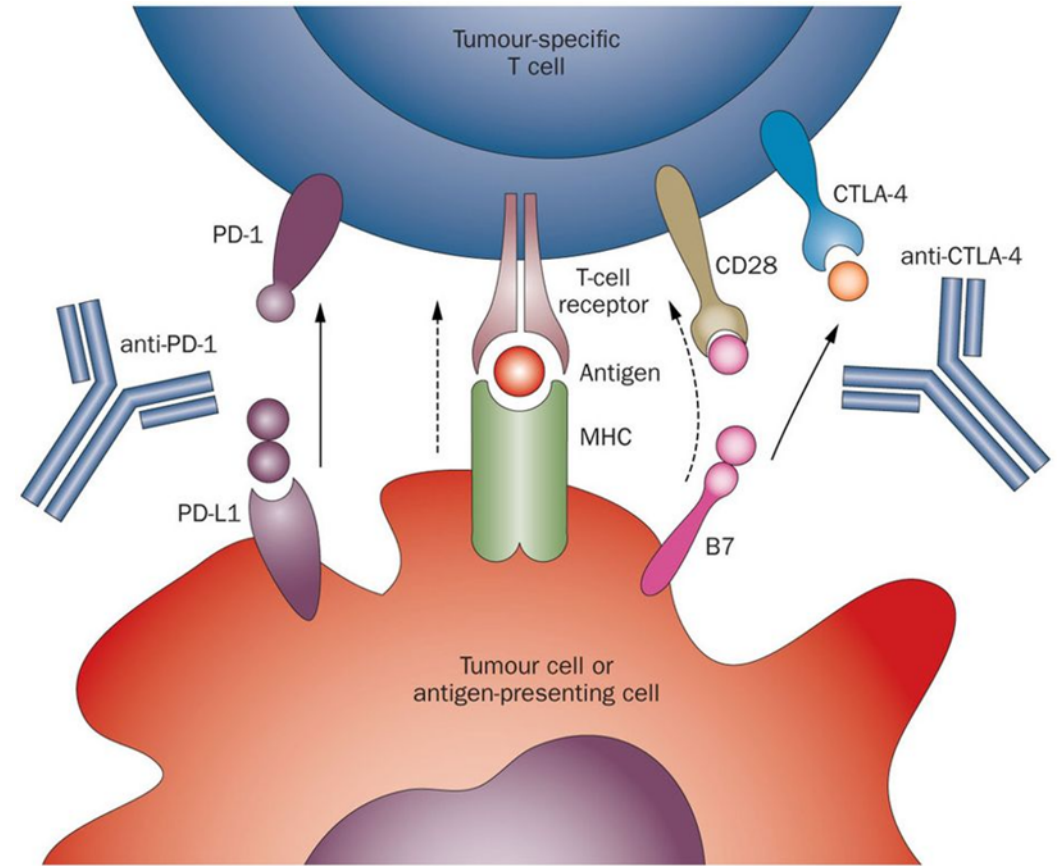




IMMUNE CHECKPOINT BLOCKADE

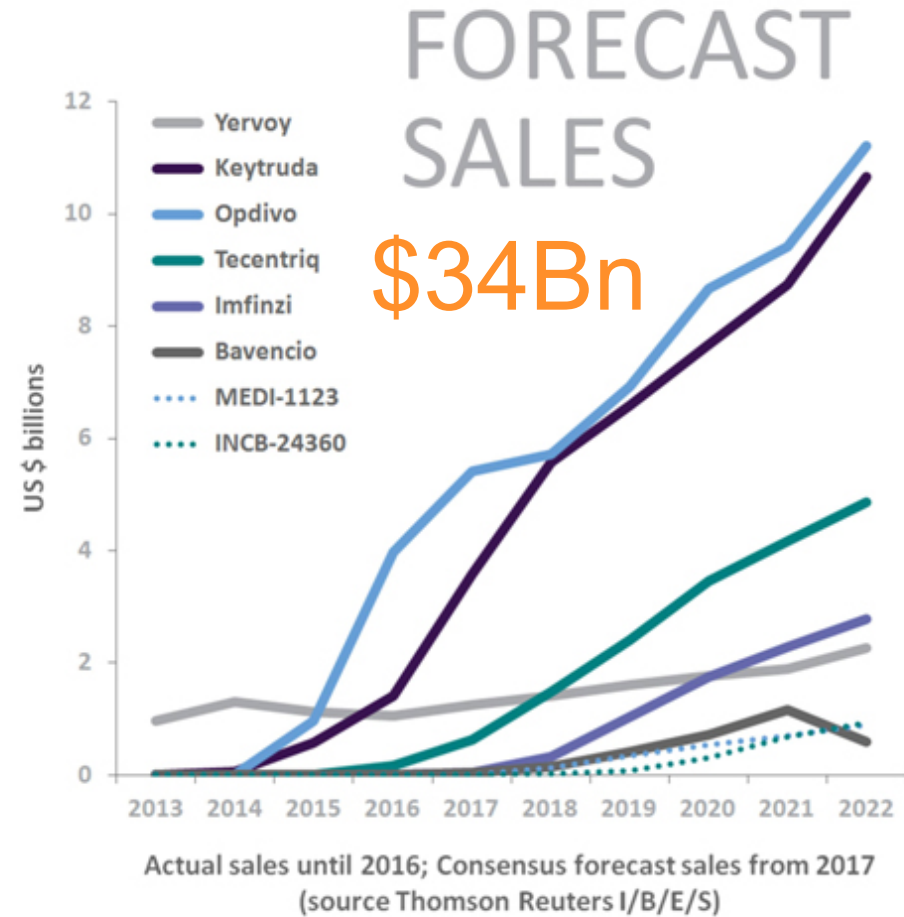
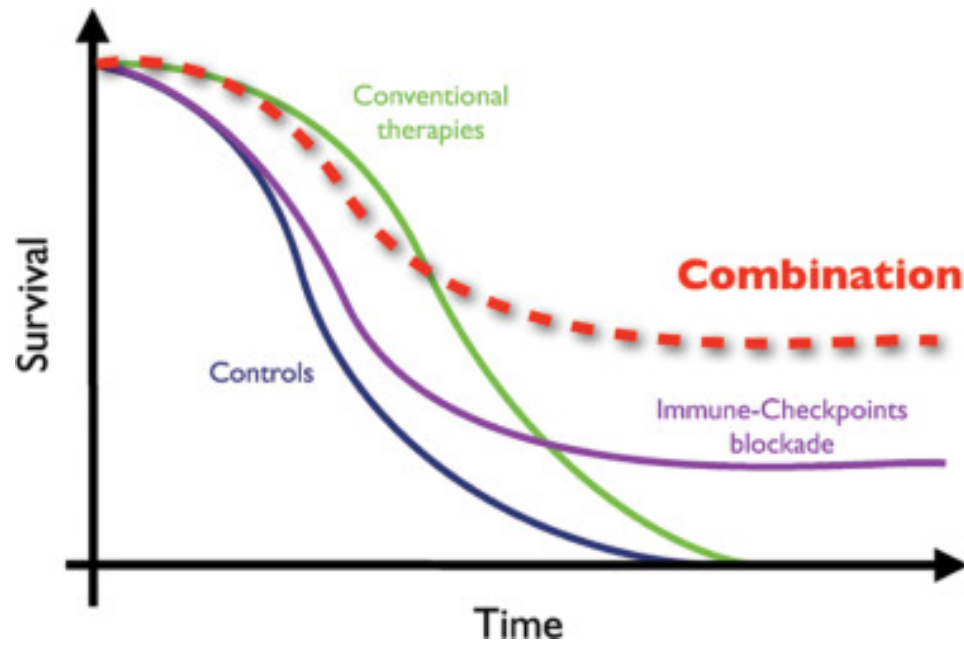


2018 Nobel Prize in Physiology or Medicine awarded to immunologists James Allison and Tasuku Honjo



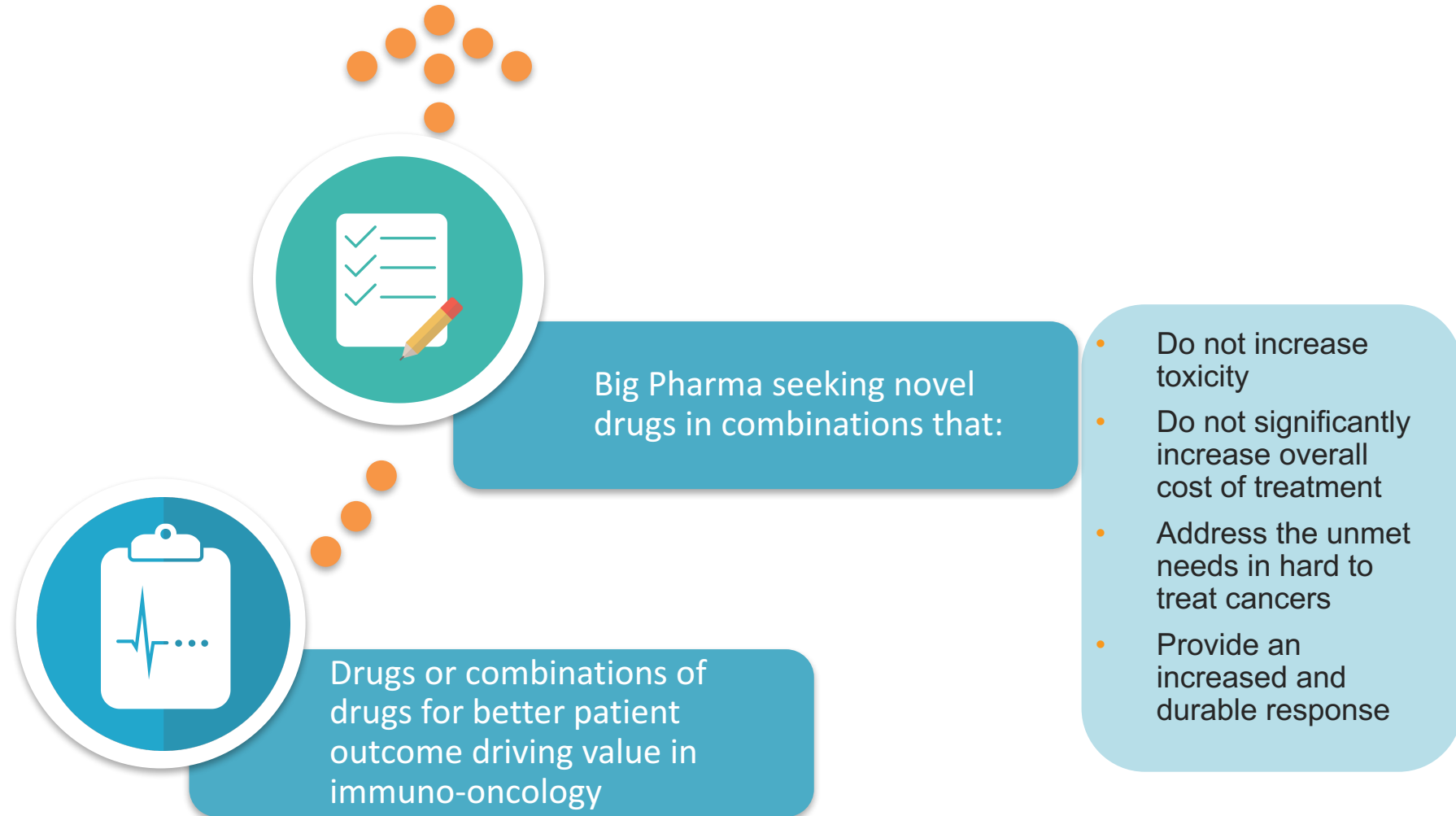


CANCER IMMUNOTHERAPY MARKET





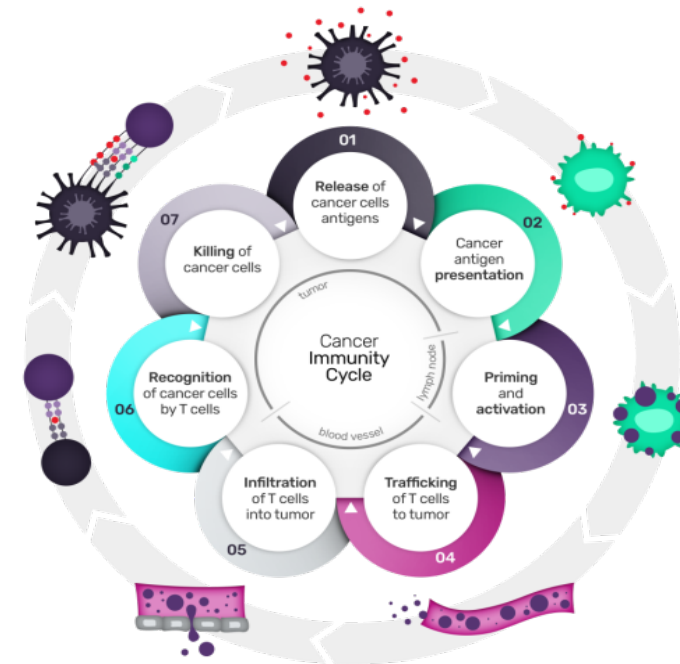
IMMUNOBODY and MODITOPE





MEETING THE NEED FOR EFFECTIVE THERAPEUTIC CANCER VACCINES

- ▶ Key challenge is to stimulate an effective T cell response to reject or kill the growing tumour
- ▶ Most vaccine strategies only stimulate low frequency, low avidity T cell responses that fail to control tumour growth
- ▶ Scancell's novel therapies stimulate **high avidity** CD8 and/or CD4 T-cells that efficiently kill tumours



Ref: Chen and Mellman 2013

TWO DIFFERENTIATED PLATFORMS

IMMUNOBODY®

- ▶ DNA-based platform generates high avidity CD8 T-cells by presenting T-cell epitopes of known cancer antigens through a unique dual mode of action

MODITOPE®

- ▶ Modified peptides that generate potent killer CD4 T-cells to target antigens induced by stress-induced post-translational modifications (siPTM vaccines)



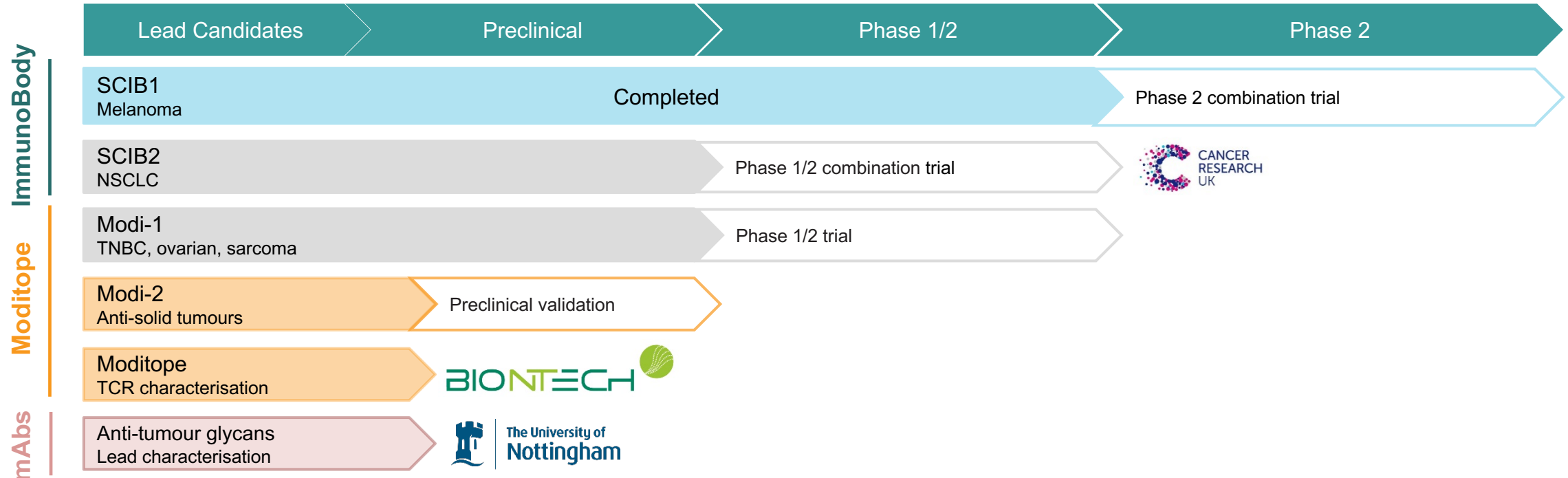
DEVELOPMENT PIPELINE

IMMUNOBODY®

- ▶ **SCIB1:** Targets malignant melanoma. Phase 1/2 study completed with strong survival data. Phase 2 combination trial with immune checkpoint inhibitor planned for Q4 2018.
- ▶ **SCIB2:** Targets NSCLC. Phase 1/2 combination trial with immune checkpoint inhibitor to be funded and sponsored by Cancer Research UK (CRUK).

MODITOPE®

- ▶ **Modi-1:** Manufacturing process development initiated. Phase 1/2 trial in TNBC, ovarian and sarcoma planned for 2019.
- ▶ **Modi-2:** Targets multiple solid tumours. Preclinical development of selected epitopes planned throughout 2018.
- ▶ **TCR collaboration:** To clone and characterise T cell receptors against Modi-1 specific epitopes.

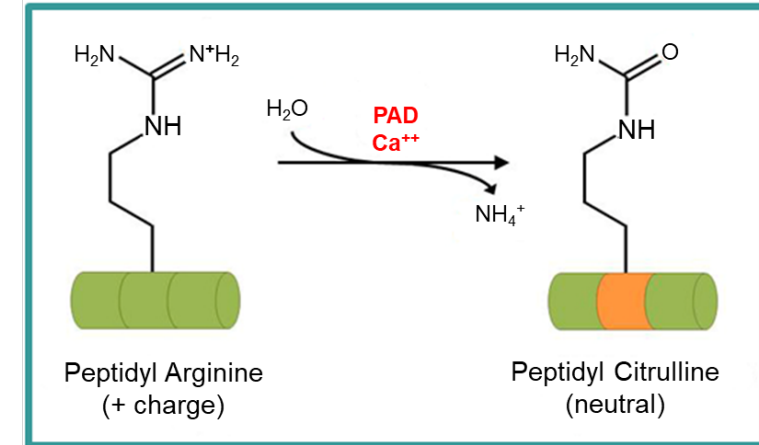




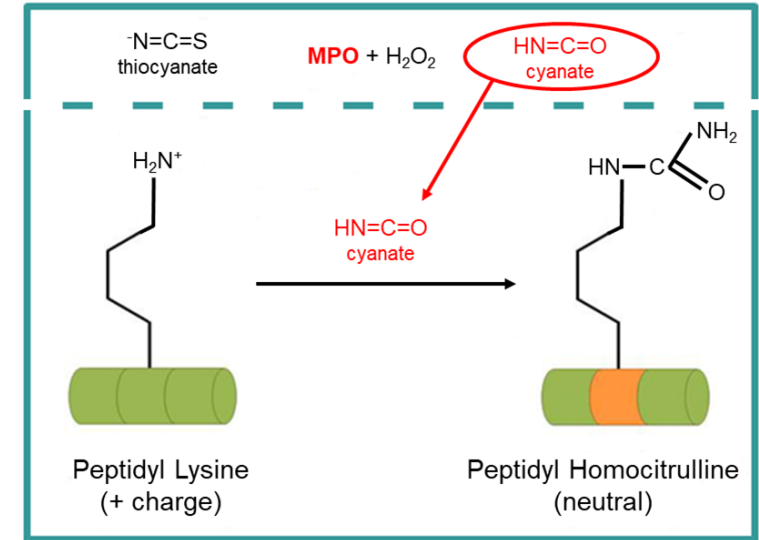
Stress-Induced Post-translational Modifications siPTM

- ▶ One such modification involves the process of **CITRULLINATION**
 - ▶ The alteration of proteins due to enzymatic conversion of arginine residues to citrulline
 - ▶ Citrullination occurs as a result of a degradation and 'recycling' process called **autophagy** that is induced in stressed cells, including cancer cells
 - ▶ Citrullinated epitopes presented on **MHC class II**
 - ▶ Patent awarded in Europe, Japan, China, Australia; still being pursued in US but attorney confident we will get broad claims

- ▶ Another modification involves the process of **HOMOCITRULLINATION**
 - ▶ the alteration of proteins due to non-enzymatic conversion of lysine residues to homocitrulline
 - ▶ Homocitrullination occurs as a result of MPO released by myeloid-derived suppressor cells (MDSC) which converts thiocyanate to cyanate in the presence of H_2O_2
 - ▶ Cyanate diffuses into tumour cells and results in spontaneous homocitrullination of cytoplasmic proteins
 - ▶ These proteins are degraded during **autophagy** and homocitrullinated epitopes presented on **MHC class II**
 - ▶ Patent filed with broad claims in cancer and composition of matter for any use of homocitrullinated peptides



PAD = peptidylarginine deiminase



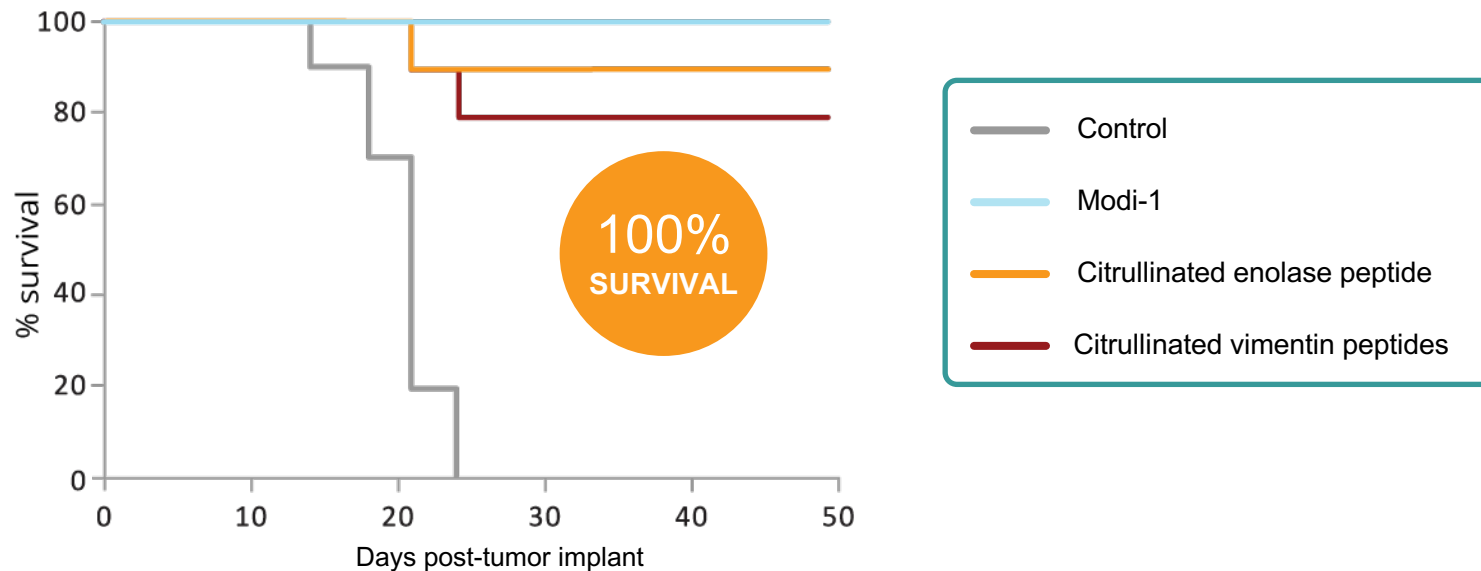
MPO = myeloperoxidase



MODITOPE® LEAD CANDIDATE

Modi-1

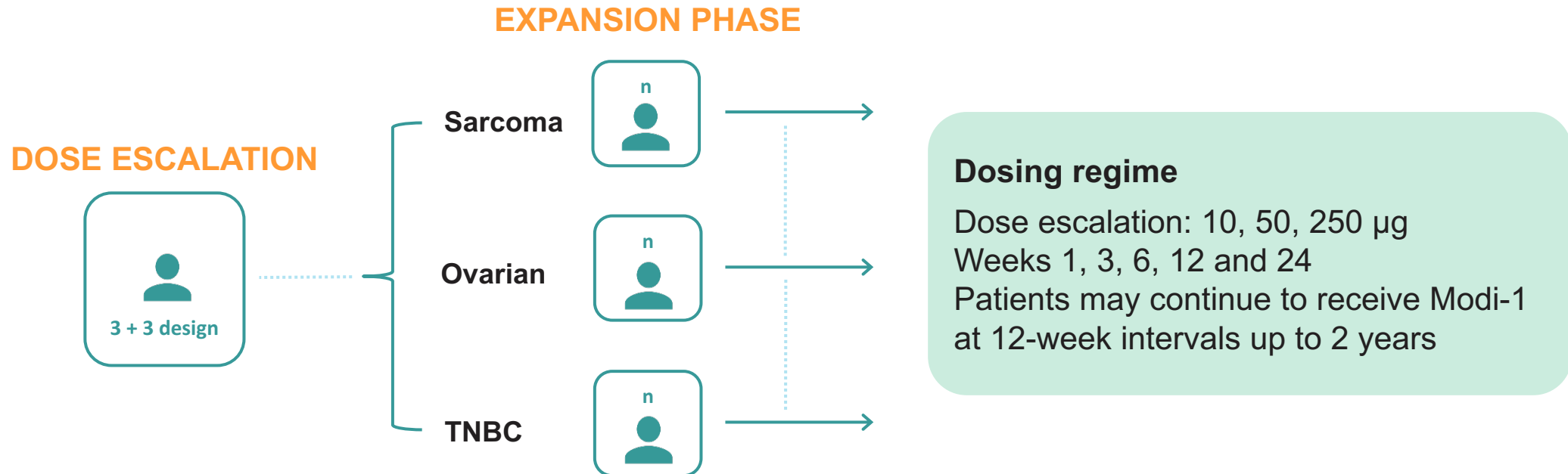
- ▶ Consists of:
 - ▶ Two citrullinated vimentin peptides (Vim-1 and Vim-2)
 - ▶ One citrullinated enolase peptide (Eno-1)
- ▶ Vimentin and enolase targets are highly expressed in triple negative breast cancer (TNBC) (90%), ovarian cancer (95%), and sarcoma (100%) - all with high unmet medical need
- ▶ Modi-1 induced potent anti-tumour responses in mice with established melanoma (B16)
- ▶ **A single immunization of Modi-1 resulted in a 100% survival rate in animal models**

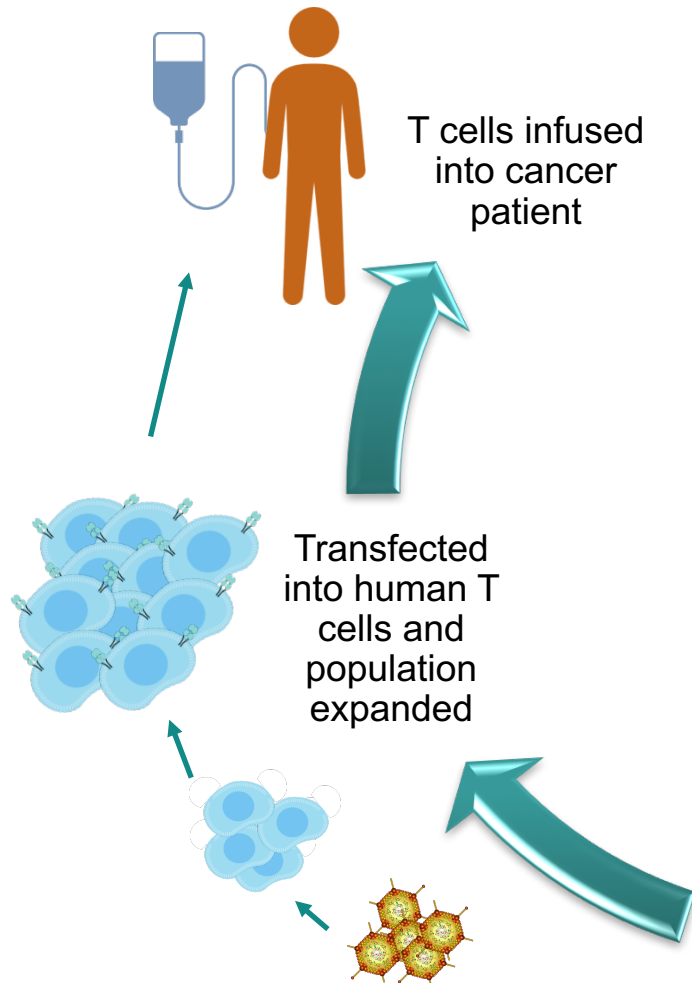




PATIENT POPULATION

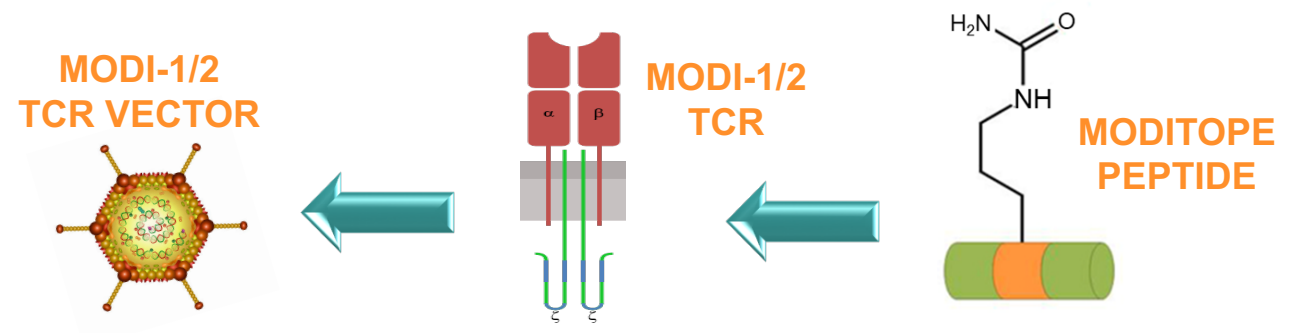
- ▶ Patients with tumours with high vimentin or enolase expression (e.g., sarcoma, triple negative breast cancer, ovarian)
- ▶ Failed or intolerant to standard of care therapies





ADVANTAGES OF CITRULLINATED & HOMOCITRULLINATED ANTIGEN-SPECIFIC TCRS

- ▶ Citrullinated & homocitrullinated antigens are expressed by a wide range of tumours
- ▶ Citrullinated & homocitrullinated antigen-specific T cells recognise the non-polymorphic HLA-DP4 so are applicable to at least 70% of patients
- ▶ Citrullinated and homocitrullinated antigen-specific T cells stimulate potent anti-tumour immunity





MODITOPE MILESTONES

EXTERNAL VALIDATION OF MODITOPE® PLATFORM

INTERNAL PROJECTS ADVANCED AND EXPANDED

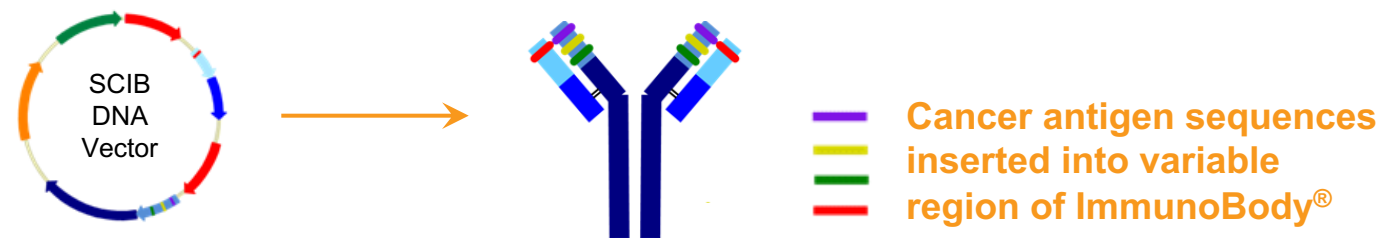
MODITOPE®

- ▶ Research collaboration to develop T-cell based therapies established with BioNTech
- ▶ License agreed with ISA Pharmaceuticals for development of Amplivant® Modi-1 conjugate therapy
- ▶ GMP manufacturer contracted for production of Modi-1/Amplivant® conjugate
- ▶ Modi-1 clinical study expected to start in CY19
- ▶ Homocitrullinated peptides under evaluation for inclusion in new Modi-2 vaccine targeting multiple solid tumours
- ▶ Strong Patent protection
- ▶ Shortlisted for CRUK Grand Challenge award; [Project Blueprint](#)



THE IMMUNOBODY[®] PLATFORM

- ▶ Proprietary patent protected platform
- ▶ Several cancer associated T cell epitopes are engineered into a human antibody framework to make a genetic antigen/antibody complex
- ▶ Delivered as a DNA plasmid using electroporation



- ▶ Nano-vesicle delivery under evaluation
- ▶ Novel dual mechanism of action based on **direct** and **cross-presentation**
- ▶ SCIB1 for melanoma (**TRP-2/gp100 melanoma associated antigens**): Phase 1/2 clinical trial complete, Phase 2 planned
- ▶ SCIB2 for lung cancer (**NY-ESO-1**): Clinical development partnership with CRUK

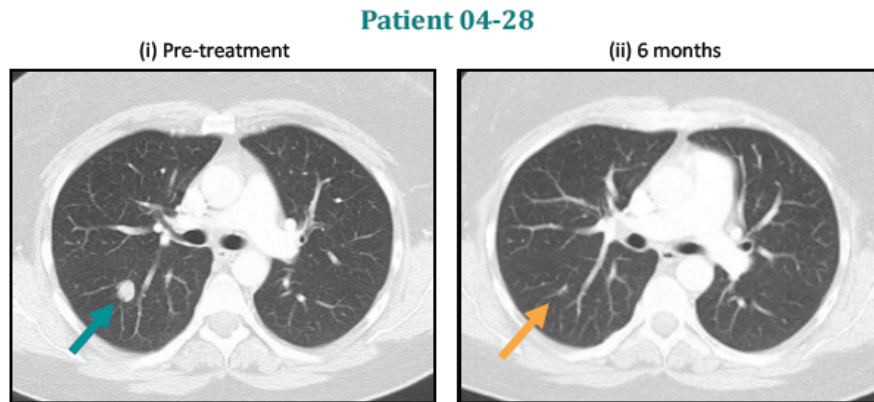


SCIB1 IN PATIENTS WITH MELANOMA

SCIB1 has an excellent safety profile with no dose-limiting toxicities and no serious adverse events related to study drug or delivery device

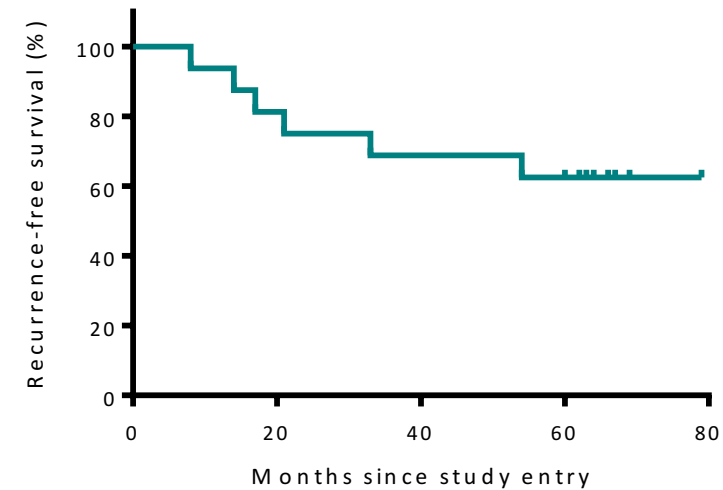
TUMOUR RESPONSE

Patient with tumour received 8 mg SCIB1 and showed a marked reduction in size of detectable lung lesions



SURVIVAL IN RESECTED PATIENTS

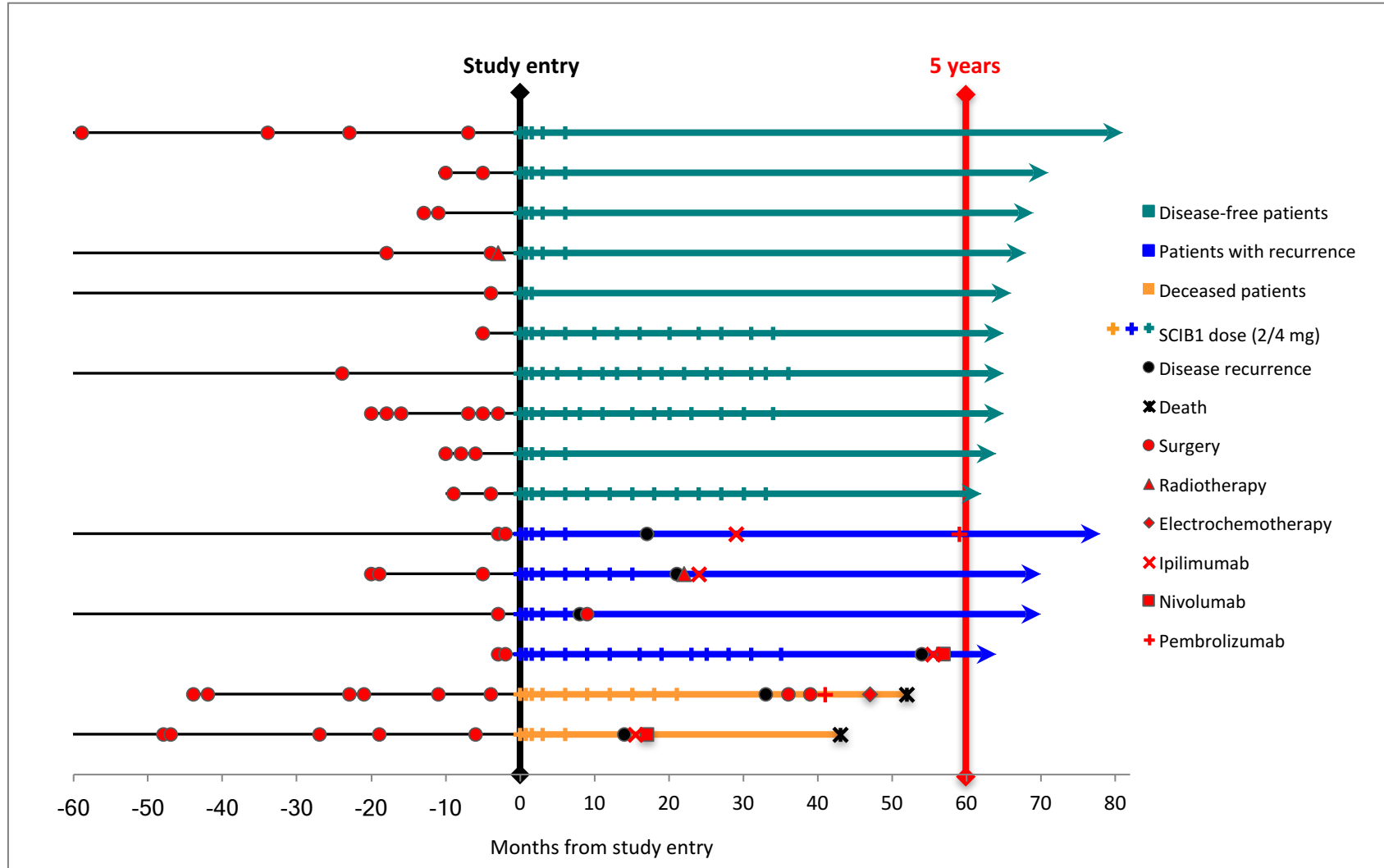
- ▶ Overall survival with SCIB1 treatment superior to historical survival rates
- ▶ 14 of 16 resected patients receiving 2-4 mg doses have survived for more than 5 years (February 2018)
- ▶ Melanoma recurrence rates are lower in SCIB1-treated patients than historical controls





SCIB1 IN MELANOMA PATIENTS

PATIENTS WITHOUT TUMOUR PRESENT AT STUDY ENTRY

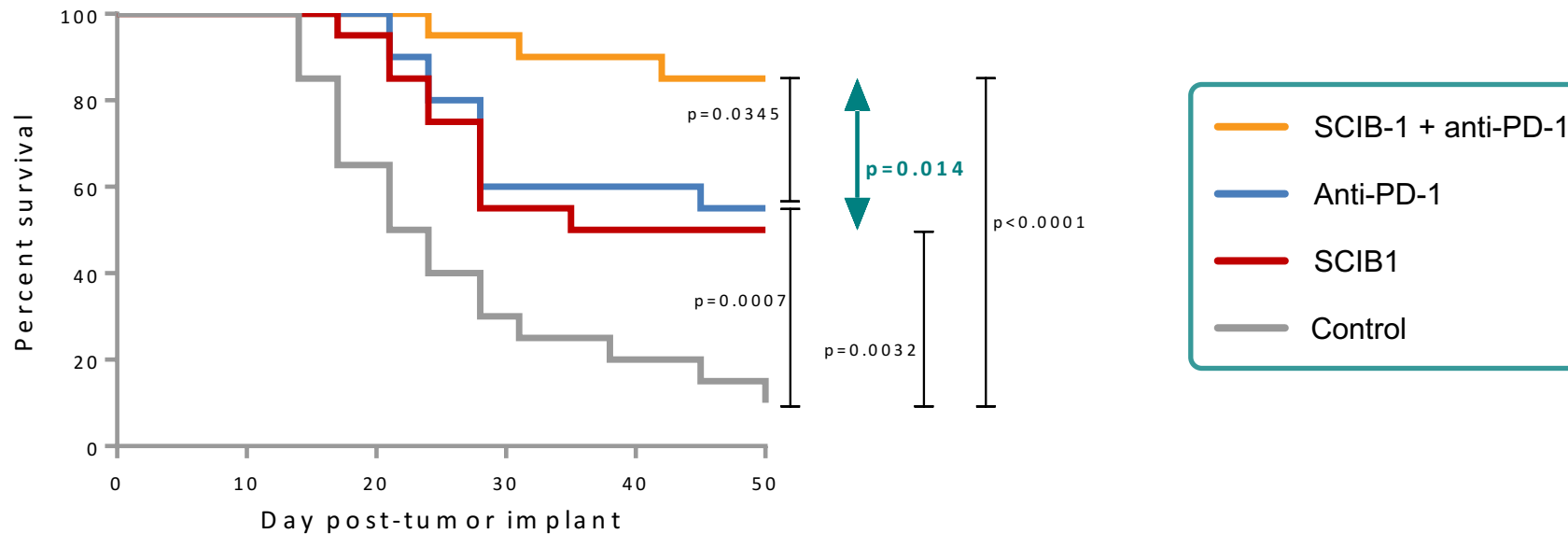




SCIB1 BOOSTS IMMUNE CHECKPOINT THERAPY

IN A MOUSE MELANOMA MODEL, SURVIVAL RATES WERE SIGNIFICANTLY BOOSTED WHEN ANTI-PD-1 THERAPY WAS COMBINED WITH SCIB1 TREATMENT

- ▶ Survival rates for SCIB1 ImmunoBody[®] monotherapy \approx anti-PD-1
- ▶ Monotherapy viable option for resected melanoma patients
- ▶ Combination therapy resulted in an 85% survival rate
- ▶ SCIB1 also upregulates PD-L1 expression and memory response

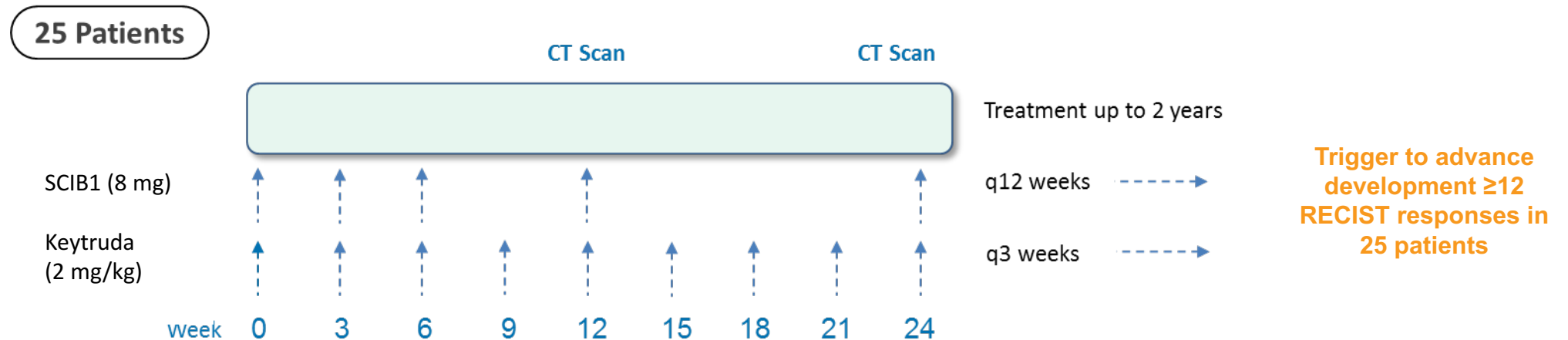




SCIB1 PLUS CHECKPOINT INHIBITOR COMBINATION PHASE 2 STUDY DESIGN

PATIENT POPULATION

- ▶ Histologically confirmed, unresectable AJCC stage III or stage IV melanoma
- ▶ No prior systemic treatment for advanced disease
- ▶ Suitable for treatment with Keytruda (pembrolizumab), with measurable disease
- ▶ Part 1 – safety run-in (n=6); Part 2 – additional 19 patients; total = 25 patients







Assumptions

- ▶ Response rate to Keytruda = 30%
- ▶ Response rate of interest for combination = 55%



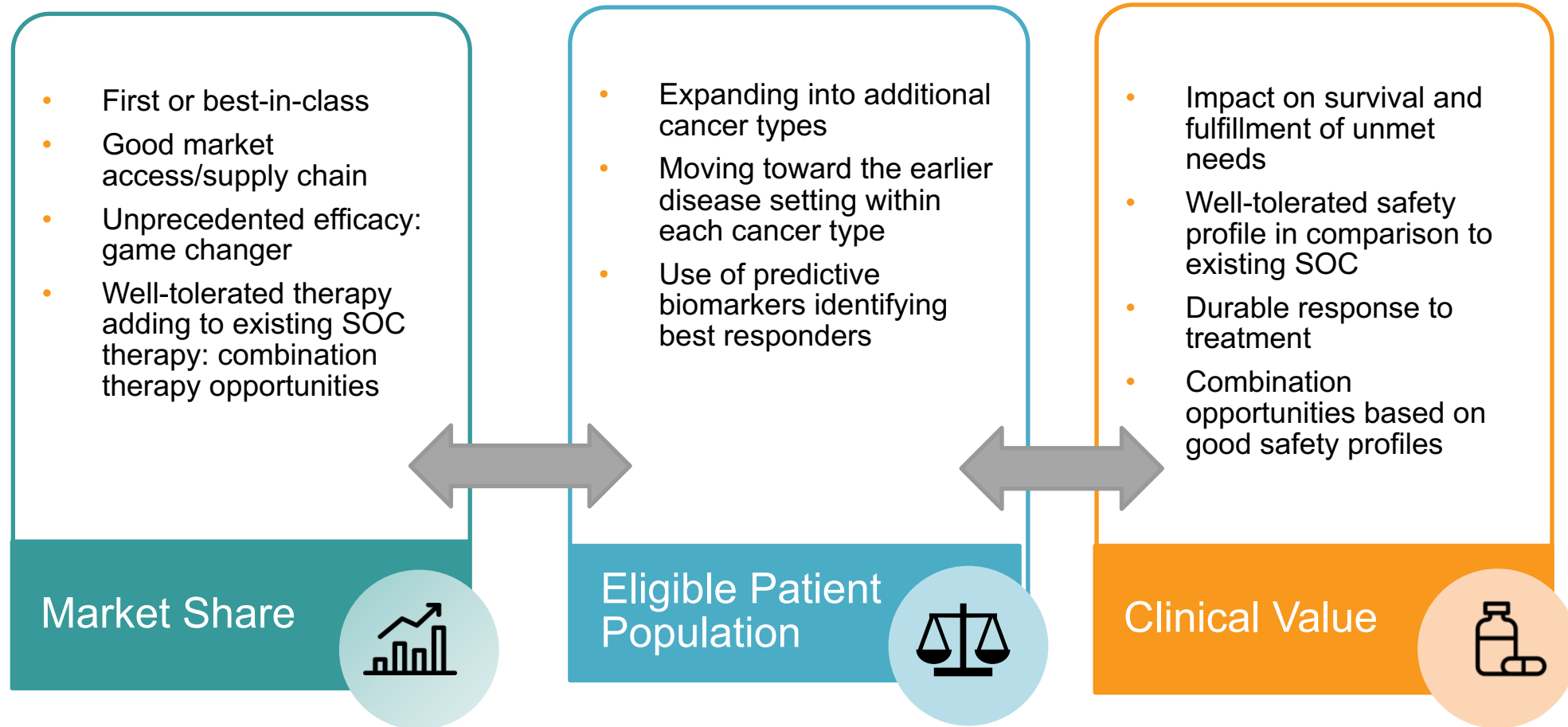
SCIB1 IND REVIEW PROCESS

- ▶ IND submitted 
- ▶ Reviewed by FDA
 - ▶ SCIB1 clinical and toxicology questions answered during review process 
 - ▶ CMC questions under control 
- ▶ Ichor TriGrid v2.0 device Master File
 - ▶ Device-specific questions
 - ▶ Responses being prepared by Ichor in consultation with Scancell
- ▶ Complete response required for review by FDA
- ▶ Continue to plan for study start in UK and US, subject to regulatory approval 





COMMERCIAL SUCCESS IN THE ONCOLOGY MARKET





IMMUNOBODY®

SCIB1

- ▶ In combination with checkpoint inhibitors in patients with late stage disease to increase efficacy without compromising safety
- ▶ As monotherapy in patients with resected disease (adjuvant setting) to delay or prevent recurrence

SCIB2

- ▶ Lung cancer huge unmet medical need; deaths per year greater than melanoma, colon, breast and prostate cancers combined
- ▶ Checkpoint inhibitors less effective in lung cancer, with 80% of patients requiring a better SOC

MODITOPE®

Modi-1 & Modi-2

- ▶ siPTM vaccine class
- ▶ Innovative mechanism of action potentially targets all solid tumours
- ▶ Modi-1 and Modi-2 will target tumours that are unresponsive to existing immunotherapy (turning “cold” tumours to “hot”)
- ▶ Identification of Modi-specific TCRs provides a novel pathway for CD4-based TCR therapy
- ▶ Novel combinations to prevent ‘tumour escape’



Operational

- ▶ SCIB2 clinical development partnership with Cancer Research UK (CRUK)-*December 2017*
- ▶ Moditope research Collaboration with BioNTech to develop T-cell receptor therapies- *January 2018*
- ▶ Licensing of ISA Pharmaceuticals Amplivant adjuvant technology for Modi-1- *February 2018*
- ▶ Contracting PolyPeptide Group for good manufacturing practice (GMP) manufacture of Modi-1- *March 2018*
- ▶ In-licensing of novel monoclonal antibodies against tumour associated glycans and antibody engineering technology- *April 2018*
- ▶ *Exercise of commercial option to Ichor TriGrid 2.0 electroporation delivery device for SCIB1*

Financial

- ▶ Cash at bank on 30th April 2018 was £10,303,168 (2017: £2,672.335)
- ▶ Overall loss for the year £4,194,509 (2017: £3,544,979)
- ▶ Share capital placing:
 - ▶ Placement £4.7m net of costs-May 2017
 - ▶ Placement £6.9m net of costs-April 2018
 - ▶ *Open Offer £1.1m net of costs-May 2018*
- ▶ *Exercise of share options by Ichor £143,307- July 2018*



IMMUNOBODY®

SCIB1

- ▶ SCIB1/checkpoint inhibitor Phase 2 US/UK combination study in late stage melanoma, planned to start 1H19, subject to regulatory submissions
 - ▶ Opening of IND
 - ▶ Commencement of the Phase 2 combination trial utilising Ichor TriGrid v2.0 electroporation device

SCIB2

- ▶ CRUK development activities for initiation of SCIB2 Phase 1/2 study for NSCLC

MODITOPE®

Modi-1

- ▶ Preparation for the First-In-Human study with Modi-1 in patients with TNBC, ovarian cancer and sarcoma planned to start CY19
- ▶ Identification of Modi-specific TCRs in collaboration with BioNTech

Modi-2

- ▶ Pre-clinical development for multiple solid tumour indications
- ▶ Extension of patent portfolio



FUTURE VALUE DRIVERS

2 PLATFORMS, 4 LEAD PRODUCTS + 5 CORE ACTIVITIES

CLINICAL DATA

- Generate meaningful clinical data to address unmet needs: clinical read-outs (SCIB1 Phase 2 & Modi-1 Phase 1/2 pt 1) anticipated in next 2 years

PIPELINE EXPANSION

- Extend utility of Moditope platform beyond Modi-1 and Modi-2 in association with key industry players e.g., TCRs
- Lead generation and optimisation of anti-glycan mAbs

TECHNOLOGY PARTNERSHIPS

- Evaluate and implement enabling technologies e.g., nano-vesicle delivery (Immunobody), and adjuvant (Moditope), to aid and de-risk development

CLINICAL PARTNERSHIPS

- Establish relationships with key opinion leaders and clinical networks to ensure utility in clinical practice e.g., CRUK and patient advocacy groups (Addario)

INDUSTRY PARTNERSHIPS

- Explore synergies with large Pharma/Biotech companies in identifying combination therapies for optimal outcomes e.g., checkpoint inhibitors





Contact

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